

K032144

OCT - 1 2003

7.0 510(k) Summary

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2597
Contact: Amy Smith, RA Specialist

DEVICE NAME: Perifix® Catheter Connector

COMMON OR USUAL NAME: Anesthesia Catheter Connector

DEVICE CLASSIFICATION: Class II per Code of Federal Regulations, Title 21, § 868.5120 – Anesthesia Conduction Catheter, 868.5140 - Anesthesia Conduction Catheter Kit

PREDICATE DEVICE: B. Braun Medical Inc.; Perifix Catheter Connector; **K022019**

DESCRIPTION: The Perifix Catheter Connector is a connecting device used to connect an anesthesia conduction catheter (most commonly an epidural or nerve block catheter) to a luer device for the administration of anesthetic fluids. Catheter connectors are commonly used in epidural anesthesia kits and nerve block kits.

The Perifix Catheter Connector will be available in two different configurations. The first configuration is the one cleared in 510(k) K022019. This new configuration is the same as the previously cleared device except it has a slightly larger inner diameter to more easily accept 18 – 19 gauge Perifix catheters, and the device is made with clear/translucent materials to easily distinguish it from the first configuration which is yellow.

The Perifix Catheter Connector is approximately 1.77 inches long and 0.43 inches in diameter. The connector consists of a luer device on one end for the attachment of a mating luer device, a threading hole, compressible catheter channel and hinged clamp mechanism.

INTENDED USE: A connection device used to provide various anesthetic and fluid administration devices with a single, common access point to 18 - 19 gauge Perifix catheter for delivery of anesthetics. The connector is used in conjunction with 18 - 19 gauge Perifix catheters for continuous administration of anesthetic agents.

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**SUBSTANTIAL
EQUIVALENCE:**

The Perifix® Catheter Connector is substantially equivalent to the B. Braun Medical Inc. Perifix Catheter Connector, K022019. The Perifix Catheter Connector will be available in two different configurations. The first configuration is the one cleared in K022019. The new configuration is the same as the predicate device except it has a slightly larger inner diameter to more easily accept 18 – 19 gauge Perifix catheters, and the device is made with clear/translucent materials to easily distinguish it from the first configuration which has yellow components. These minor changes do not raise any new issues of safety or efficacy.



OCT - 1 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Amy Smith
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K032144
Trade/Device Name: Perifix Catheter Connector
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ, BSO
Dated: June 10, 2003
Received: June 14, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner".

Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

2.0 Indications for Use Statement

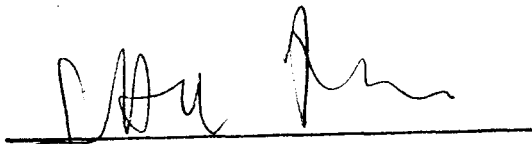
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510(k) Number (if known): K032144

Device Name: Perifix® Catheter Connector

Indications For Use:

A connection device used to provide various anesthetic and fluid administration devices with a single, common access point to 18 - 19 gauge Perifix catheter for delivery of anesthetics. The connector is used in conjunction with 18 - 19 gauge Perifix catheters for continuous administration of anesthetic agents.


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032144

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

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